

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: 930008-2208 (BOE0004US.NP)  
Inventors: Klokke et al.  
Serial No.: 10/577,569  
Filing Date: Not Yet Assigned  
Examiner: Not Yet Assigned  
Customer No.: 26259  
Group Art Unit: Not Yet Assigned  
Confirmation No.: Not Yet Assigned  
Title: Pharmaceutical Active-  
Ingredient-Containing Formulation  
with Coating

**Electronically Submitted via EFS-Web**

Date: October 4, 2007

I hereby certify that this paper is being electronically  
submitted on the date indicated above to the  
Commissioner for Patents, U.S. Patent &  
Trademark Office

By Jane Massey Licata  
Typed Name: Jane Massey Licata, Reg. No. 32,257

U.S. Patent and Trademark Office  
P.O. Box 2327  
Arlington, VA 22202-0327

Dear Sir:

**RENEWED PETITION UNDER 37 CFR §1.47(a)**

In response to the "Decision", a response to which is due  
**January 7, 2008** (copy attached), applicants petition pursuant to 37  
CFR §1.47(a) for the Office to accept the Declaration and Power of  
Attorney Form for the above-referenced application which has been

Attorney Docket No.: BOE0004US.NP  
Inventors: Klokke et al.  
Serial No.: 10/577,569  
Filing Date: Not Yet Assigned  
Page 2

signed by inventors Klokke, Zellner and Dauer but not by inventor Rillmann.

As stated in the Petition filed with applicants Response to Notification of Missing Requirements on February 21, 2007, applicants' counsel accepted the representation and handling of this application on February 20, 2007 and were advised by Boeters & Lieck (the German representative), they were unable to obtain inventor Rillmann's signature on the Declaration and Power of Attorney form.

On February 23, 2007, a letter was sent to inventor Rillmann via Federal Express containing the Declaration and Power of Attorney form for signature. Confirmation of delivery was received from Federal Express on February 26, 2007.

Copies of applicants' Response to Notification of Missing Requirements filed February 21, 2007, the letter sent to inventor Rillmann via Federal Express containing the Declaration and Power of Attorney form for signature dated February 23, 2007 and letter from Boeters & Lieck confirming the last known address of inventor, Rillmann are provided.

Attorney Docket No.: BOE0004US.NP  
Inventors: Klokke et al.  
Serial No.: 10/577,569  
Filing Date: Not Yet Assigned  
Page 3

The Rillmann Declaration and Power of Attorney was not accepted by the USPTO pursuant to the Decision dated September 5, 2007. Another copy of the joint Declaration was furnished to Rillmann on October 2, 2007, which he refused to sign.

Inventor Rillmann prepared and executed his own Declaration (listing himself as an inventor) and executed the Declaration signed only by himself of July 5, 2007. A response to Missing Parts was filed on July 17, 2007 with this Declaration and a Declaration signed by the three co-inventors. The Rillmann Declaration and Power of Attorney was not accepted by the USPTO pursuant to the Decision dated September 5, 2007.

Inventor Rillmann continued to refuse to sign the joint Declaration and Power of Attorney. This is evidenced repeatedly throughout the correspondence sent to Rillmann directly to his last known address on February 23, 2007 and October 2, 2007 as well as through his counsel on May 23, 2007, November 20, 2007, December 13, 2007 and January 4, 2008.

Additionally, further refusal to sign the Declaration and Power of Attorney is evidenced by Rillmann in a Declaration and Power of Attorney he prepared and executed the instant application

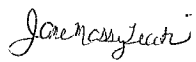
Attorney Docket No.: BOE0004US.NP  
Inventors: Klokke et al.  
Serial No.: 10/577,569  
Filing Date: Not Yet Assigned  
Page 4

which listed him as a sole inventor. This Declaration and Power of Attorney was duly executed by Rillmann on July 5, 2007. Again, this Declaration and Power of Attorney was not accepted by the USPTO pursuant to the Decision dated September 5, 2007.

Therefore, Applicants submit with this response and petition, a Declaration of Hubert Leger, proof of the pertinent facts regarding their inability to find or reach non-signing inventor Rillmann and the requisite fees under 37 CFR §1.17(I) and 1.17(a)(3). The last known address of non-signing inventor Thomas Rillmann is Gustav-Ulrich-Str. 46, D-76753 Bellheim, Germany.

Applicants have met all of the requirements as set forth in 37 CFR 1.47(a) and respectfully request the Response to Notification of Missing Requirements filed on July 17, 2007 be entered and the filing date granted.

Respectfully submitted,

  
Jane Massey Licata  
Registration No. 32,257

Date: January 4, 2008

LICATA & TYRRELL P.C.  
66 E. Main Street  
Marlton, New Jersey 08053

(856) 810-1515



07 NOV 2007

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents  
United States Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450  
www.uspto.gov

FROMMER LAWRENCE  
& HAUG LLP

2007 NOV 14 A 7:52

Ronald R. Santucci  
Frommer Lawrence & Haug  
745 Fifth Avenue  
New York NY 10151

DOCKETED

Docket System ☒  
Status Report ☒  
Docket Book ☒

In re Application of :  
KLOKKERS et al. :  
Application No.: 10/577,569 :  
PCT No.: PCT/EP2004/012230 :  
Int. Filing Date: 28 October 2004 :  
Priority Date: 31 October 2003 :  
Attorney Docket No.: 930008-2208 :  
For: PHARMACEUTICAL ACTIVE-INGREDIENT- :  
CONTAINING FORMULATION WITH COATING :

DECISION

This decision is in response to the petition under 37 CFR 1.47(a) filed 04 October 2007 in the United States Patent and Trademark Office (USPTO).

**BACKGROUND**

On 28 October 2004, applicants filed international application PCT/EP2004/012230, which designated the United States and claimed a priority date of 31 October 2003. A copy of the international application was communicated from the International Bureau to the USPTO on 12 May 2005. The thirty-month period for paying the basic national fee in the United States expired at midnight on 01 May 2006 (30 April 2006 being a Sunday).

On 27 April 2006, applicants filed a submission for entry into the national stage in the United States which was accompanied by, *inter alia*, the U.S. Basic National Fee and a translation of the application into English.

On 26 August 2005, the United States Designated/Elected Office (DO/EO/US) mailed a NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 (Form PCT/DO/EO/905) indicating, *inter alia*, that an oath or declaration of the inventors in compliance with 37 CFR 1.497(a)-(b) was required.

On 21 February 2007, applicants filed a petition under 37 CFR 1.47(a) which was accompanied by, *inter alia*, a declaration signed by all of the inventors except for Thomas Rillmann, a letter from a Dr. Forstmeier to Applicant's United States attorney, Ms. Massey Licata, dated 20 February 2007.

On 28 March 2006, a decision was mailed dismissing applicants' petition under 37 CFR

Application No.: 10/577,569

-2-

1.47(a) without prejudice. The decision indicated, *inter alia*, that applicant had failed to provide factual proof that the missing joint inventor refuses to execute the application or cannot be reached after diligent effort. The decision set a two-month extendable period for reply.

On 17 July 2007, applicants filed a submission which was accompanied by, *inter alia*, a declaration of inventors signed by Thomas Rillmann.

On 05 September 2007, a decision was mailed dismissing applicants' petition under 37 CFR 1.47(a) as moot since a 37 CFR 1.497 declaration had been executed by all the joint inventors. The decision also indicated that the declaration of inventors signed by Thomas Rillmann filed 17 July 2007 was not in compliance with 37 CFR 1.497(a)-(b) since it did not identify all of the inventors and that a new declaration signed by Thomas Rillmann in compliance with 37 CFR 1.497(a)-(b) was required.

On 04 October 2007, applicants submitted the instant petition under 37 CFR 1.47(a), which was accompanied by, *inter alia*, a declaration of facts by Hubert Leger.

#### DISCUSSION

A petition under 37 CFR 1.47(a) must be accompanied by: (1) the fee under 37 CFR 1.17(b); (2) factual proof that the missing joint inventor refuses to execute the application or cannot be reached after diligent effort; (3) a statement of the last known address of the missing inventor; and (4) an oath or declaration by each 37 CFR 1.47(a) applicant on his or her own behalf and on behalf of the non-signing joint inventor.

Items (1), (3), and (4) have been met.

Item (2) has not been satisfied. MPEP § 409.03(d) states in part:

A refusal by an inventor to sign an oath or declaration when the inventor has not been presented with the application papers does not itself suggest that the inventor is refusing to join the application unless it is clear that the inventor understands exactly what he or she is being asked to sign and refuses to accept the application papers.

The declaration of facts by Mr. Leger filed 04 October 2007 makes it clear that Mr. Rillmann understands exactly what he is being asked to sign. However, it has not been established that Mr. Rillmann refuses to sign. While Mr. Rillmann signed a declaration of inventors listing only himself as an inventor, it has not been established that he refuses to sign a declaration of inventors listing all of the inventors. The declaration of Mr. Leger states that a facsimile was sent to Mr. Rillmann's attorney on 02 October 2007 informing him of the problem with the declaration executed by Mr. Rillmann and requesting that Mr. Rillmann return an executed version of the original declaration before 04 October 2007. However, two days is not a sufficient amount of time for a reply. If no response is received from Mr. Rillmann's attorney, some sort of follow-up communication would be required. Additionally, the statement of facts is not

Application No.: 10/577,569

-3-

sufficient because it must be made by someone having first-hand knowledge of the facts recited herein. MPEP § 409.03(d). Mr. Leger does not appear to have first-hand knowledge of all of the facts recited. For example, someone other than Mr. Leger sent the facsimile to Mr. Rillmann's attorney on 02 October 2007.

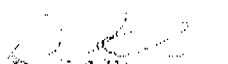
#### CONCLUSION

For the above reasons, applicants' petition under 37 CFR 1.47(a) is **DISMISSED** without prejudice.

For the above reasons, that portion of the decision mailed 05 September 2007 which dismissed applicants' petition under 37 CFR 1.47(a) as moot is hereby VACATED.

If reconsideration on the merits of this petition is desired, a proper response must be filed within TWO (2) MONTHS from the mail date of this decision. **Failure to timely file the proper response will result in abandonment of this application.** Any reconsideration request should include a cover letter entitled "Renewed Petition Under 37 CFR 1.47(a)". No additional petition fee is required. Extensions of time may be obtained under 37 CFR 1.136(a).

Please direct further correspondence with respect to this matter to Mail Stop PCT, Commissioner for Patents, Office of PCT Legal Administration, P.O. Box 1450, Alexandria, Virginia 22313-1450, with the contents of the letter marked to the attention of the Office of PCT Legal Administration.

  
Daniel Stemmer  
Legal Examiner  
PCT Legal Affairs  
Office of Patent Cooperation Treaty  
Legal Administration  
Telephone: (571) 272-3301  
Facsimile: (571) 273-0459

ATTORNEY DOCKET NUMBER

930008-2209 (BOE0004US.NP)

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

10/577,569

**TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A SUBMISSION UNDER 35 U.S.C. 371**

INTERNATIONAL APPLICATION NO.  
PCT/EPO04/12230

INTERNATIONAL FILING DATE  
October 28, 2004

PRIORITY DATE CLAIMED  
October 31, 2003

**TITLE OF INVENTION**

Pharmaceutical Active-Ingredient-Containing Formulation with Coating

**APPLICANT(S) FOR DO/EO/US**

Klokkers et al.

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☐ This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
2. ☒ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (24) indicated below.
4. ☐ The US has been elected (Article 31).
5. ☐ A copy of the International Application as filed (35 U.S.C. 371 (c)(2))
  - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ has been communicated by the International Bureau.
  - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
  - a. ☐ is attached hereto.
  - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
  - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ have been communicated by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).
11. ☐ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☐ A copy of the International Search Report (PCT/ISA/210).

**Items 13 to 23 below concern document(s) or information included:**

13. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☐ A **FIRST** preliminary amendment.
16. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
17. ☐ A substitute specification.
18. ☐ A power of attorney and/or change of address letter.
19. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825.
20. ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
21. ☐ A second copy of the English language translation of the International Application under 35 U.S.C. 154(d)(4).
22. ☒ Express Mail Label No. **EM 054665613US**



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

U.S. APPLICATION NO (if known, see 37 CFR 1.5)		INTERNATIONAL APPLICATION NO.		ATTORNEY'S DOCKET NUMBER	
10/577,569		PCT/EPO04/12230		930008-2209 (BOE0004US.NP)	
23. Other items or information: 1) Copy of Notification of Missing Requirements; and 2) Petition Under 37 CFR 1.47(a);					
The following fees have been submitted:				CALCULATIONS	PTO USE
24. <input type="checkbox"/> Basic national fee . . . . . \$300				\$	\$0.00
25. <input type="checkbox"/> Examination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article \$0 All other situations. . . . . \$200				\$	\$0.00
26. <input type="checkbox"/> Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the International preliminary examination report by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4). . . \$0 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the as an International Searching Authority. . . . . \$100 International Search Report prepared by an ISA other than the US and provided to the previously communicated to the US by the IB. . . . . \$400 All other situations. . . . . \$500				\$	\$0.00
TOTAL OF 24, 25 and 26 =				\$	\$0.00
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole)	RATE		
- 100 =	0 /50 =	0	x \$250.00	\$	\$0.00
Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).				\$	\$130.00
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	- 20 =	0	x \$50.00	\$	\$0.00
Independent claims	- 3 =	0	x \$200.00	\$	\$0.00
MULTIPLE DEPENDENT CLAIMS (if applicable) <input type="checkbox"/> + \$360.00				\$	\$0.00
TOTAL OF ABOVE CALCULATIONS =				\$	\$130.00
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.				\$	\$0.00
<b>Petition fee</b>				\$	\$130.00
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).				\$	\$0.00
TOTAL NATIONAL FEE =				\$	\$130.00
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40 per property +				\$	\$0.00
TOTAL FEES ENCLOSED =				\$	\$260.00
				Amount to be	\$
				Amount to be	\$

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

- a. ☐ A check in the amount of \$ \_\_\_\_\_ to cover the above fees is enclosed.
- b. ☐ Please charge my Deposit Account No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_ to cover the above fees.  
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-1619. A duplicate copy of this sheet is enclosed.
- d. ☒ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

**NOTE:** Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

Jane Massey Licata, Reg. No. 32,257  
Kathleen A. Tyrrell, Reg. No. 38,350  
Licata & Tyrrell P.C.  
66 E. Main Street  
Marlton, New Jersey 08053  
Telephone: (856) 810-1515  
Facsimile: (856) 810-1454

Jane Massey Licata  
SIGNATURE

Jane Massey Licata

NAME

32,257

REGISTRATION NUMBER

February 21, 2007

DATE



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
 Address: COMMISSIONER FOR PATENTS  
 P.O. Box 1450  
 Alexandria, Virginia 22313-1450  
 www.uspto.gov

U.S. APPLICATION NUMBER NO. 10/577,569	FIRST NAME OF APPLICANT Karin Klokke FROMMER, LAWRENCE & HAUG, LLP	ATTY. DOCKET NO. 930008-2208
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Ronald R. Santucci  
 Frommer Lawrence & Haug  
 745 Fifth Avenue  
 New York, NY 10151

Docket System  
 Status Report  
 Docket Book

INTERNATIONAL APPLICATION NO. PCT/EP04/12230	
IA FILING DATE 10/28/2004	PRIORITY DATE 10/31/2003

CONFIRMATION NO. 6210

371 FORMALITIES LETTER



\*OC000000021674468\*

DOCKETED

Date Mailed: 12/21/2006

2-21-07  
 7-21-07  
**NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)**

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 04/27/2006
- English Translation of the IA filed on 04/27/2006
- Copy of the International Search Report filed on 04/27/2006
- Copy of IPE Report filed on 04/27/2006
- Preliminary Amendments filed on 04/27/2006
- Information Disclosure Statements filed on 04/27/2006
- Oath or Declaration filed on 04/27/2006
- U.S. Basic National Fees filed on 04/27/2006
- Priority Documents filed on 04/27/2006

The applicant needs to satisfy supplemental fees problems indicated below.

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date. The current oath or declaration does not comply with 37 CFR 1.497(a) and (b) in that it:
  - is not executed in accordance with either 37 CFR 1.66 or 37 CFR 1.68.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.492(h) of \$130 for a non-small entity, must be submitted with the missing items identified in this letter.

SUMMARY OF FEES DUE:

Total additional fees required for this application is \$130 for a Large Entity:

- \$130 Surcharge.

**ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.**

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web.  
<https://portal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html>

For more information about EFS-Web please call the USPTO Electronic Business Center at 1-866-217-9197 or visit our website at <http://www.uspto.gov/ebc>.

**If you are not using EFS-Web to submit your reply, you must include a copy of this notice.**

CHARITTA A BURT

Telephone: (703) 308-9140 EXT 207

**PART 1 - ATTORNEY/APPLICANT COPY**

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/577,569	PCT/EP04/12230	930008-2208

20 FEB 2007 12:19

8024 908 2198

NR. 8530 S. 2/5

FLH Docket No. 930008-2208

# DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY

(Under 37 CFR § 1.63; includes reference to PCT International Applications)

As a below named inventor, I hereby declare that:

My residence, resident, mailing address and citizenship are as stated below next to my name.

I believe I am an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention ENTITLED:

## PHARMACEUTICAL ACTIVE-INGREDIENT-CONTAINING FORMULATION WITH COATING

the specification of which:

- ☐ is attached hereto
- ☒ was filed on \_\_\_\_\_ as:
- ☒ United States Application Serial No. \_\_\_\_\_
- ☒ as a National Phase or Continuation or Continuation-in-Part or Divisional of PCT Application No. PCT/EP2004/012230, filed October 28, 2004 and designating the U.S., and published as WO 2005/041934 A on May 12, 2005
- ☐ with amendments through \_\_\_\_\_ (if applicable, give details).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56.

Thereby claim foreign priority benefits under Title 35, United States Code § 119 of any foreign application(s) for patent or inventor's certificate or of any PCT International application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application for patent or inventor's certificate or any PCT International applications designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) on which priority is claimed:

Prior Foreign/PCT Application(s) [list additional applications on separate page]:

Country (or PCT)	Application Number:	Filed (Day/Month/Year)	Priority Claimed:	
			Yes	No
DE (Germany)	103 51 301.9	31/10/2003	<input checked="" type="checkbox"/>	<input type="checkbox"/>
DE (Germany)	10 2004 014 828.7	24/03/2004	<input checked="" type="checkbox"/>	<input type="checkbox"/>

I hereby claim the benefit under 35 U.S.C. § 119(e) of any United States application listed below:

(Application Number) (Filing Date)

I hereby claim the benefit under Title 35, United States Code § 120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code § 112, I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

20. FEB. 2007 12:20

8024 908 2198

NR. 853 S. 3/5

FLH Docket No. 930008-2208

Prior U.S. (or U.S.-designating PCT) Application(s) [list additional applications on separate page]:

U.S. Serial No.: Filed (Day/Month/Year) PCT Application No. Status (patented, pending, abandoned)

I hereby appoint Ronald R. Santucci, Registration No. 28,988, and Frommer Lawrence & Haug LLP, or their duly appointed associate, my attorneys, with full power of substitution and revocation, to prosecute this application, to make alterations and amendments therein, to file continuation and divisional applications thereof, to receive the Patent, and to transact all business in the Patent and Trademark Office and in the Courts in connection therewith, and to insert the Serial Number of the application in the space provided above, and specify that all communications about the application are to be directed to the following correspondence address:

Ronald R. Santucci, Esq.  
c/o FROMMER LAWRENCE & HAUG LLP  
745 Fifth Avenue  
New York, NY 10151

Direct all telephone calls to: (212) 588-0800  
to the attention of: Ronald R. Santucci

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

## INVENTOR(S):

X Signature: Karin KlockersDate: Aug 28, 2006Full name of sole or first inventor: Karin KLOCKERSResidence: Feldkirchen-Westerham, GermanyMailing Address: Eichenstr. 2a, D-83620, Feldkirchen-Westerham, GermanyCitizenship: GermanX Signature: Marion ZellnerDate: 20.09.2006Full name of 2nd joint inventor (if any): Marion ZELLNERResidence: Egmating, GermanyMailing Address: Binsberg 15, D-85658, Egmating, GermanyCitizenship: German

X Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Full name of 3rd joint inventor (if any): Thomas RILLMANResidence: Bellheim, GermanyMailing Address: Gustav-Ullrich-Str. 46, D-76753, Bellheim, GermanyCitizenship: German

20. FEB: 2007 12:20

(=) 8024 908 2198

NR. 853 S. 4/5

FLH Docket No. 930008-2208

X Signature: Andreas Daur

Date: 04/03/06

Full name of 4th joint inventor (if any): Andreas DAUER

Mailing Address: Julius-von-Niethammer-Str. 16, D-83052 Heufeld, Germany

Residence: Heufeld, Germany

Citizenship: German

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: 930008-2208 (BOE0004US.NP)  
Inventors: Klokke et al.  
Serial No.: 10/577,569  
Filing Date: Not Yet Assigned  
Examiner: Not Yet Assigned  
Customer No: 26259  
Group Art Unit: Not Yet Assigned  
Confirmation No: 6210  
Title: Pharmaceutical Active-  
Ingredient-Containing Formulation  
with Coating

"Express Mail" Label No. EM054665613US  
Date of Deposit February 21, 2007

I hereby certify that this paper is being deposited with the  
United States Postal Service "Express Mail Post Office  
to Addressee" service under 37 CFR 1.10 on the date  
indicated above and is addressed to the Commissioner for Patents  
Post Office Box 1450, Box Missing Parts, Alexandria, VA 22313-1450

By Jane Massey Licata  
Typed Name: Jane Massey Licata, Reg. No. 32,257

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Petition Under 37 CFR §1.47(a)

Applicants petition pursuant to 37 CFR §1.47(a) for the Office  
to accept the Declaration and Power of Attorney Forms for the  
above-referenced application which have been signed by inventors  
Klokke, Zellner and Dauer but not signed by inventor Rillman.

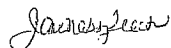


Attorney Docket No.: BOE0004US.NP  
Inventors: Klokke et al.  
Serial No.: 10/577,569  
Filing Date: Not Yet Assigned  
Page 2

Applicants' counsel accepted the representation and handling of this application on February 20, 2007. As evidenced by the attached letter from Boeters & Lieck, inventor, Rillmann refuses to sign the Declaration and Power of Attorney form.

Therefore, Applicants are submitting with this petition, the requisite fees under 37 CFR §1.17(i) and 1.17(a)(3) and respectfully request that the attached duly executed Declaration and Power of Attorney forms signed by inventors, Klokke, Zellner and Dauer be considered responsive to the Notification of Missing Requirements

Respectfully submitted,



Jane Massey Licata  
Registration No. 32,257

Date: February 21, 2007

LICATA & TYRRELL P.C.  
66 E. Main Street  
Marlton, New Jersey 08053

(856) 810-1515

BOETERS & LIECK - PATENTANWÄLTE  
- EUROPIAN PATENT AND  
- TRADEMARK ATTORNEYS

FACSIMILE: 001-856-810-1454  
Licata & Tyrrell P.C.  
Attn.: Ms Jane Massey Licata  
66 E. Main Street  
Marlton, New Jersey 08053  
USA

February 20, 2007/St  
via facsimile

URGENT

Your ref.: unknown  
Our ref.: 16508  
US Patent Application No. 10/577 569  
Hexal AG

Dear Ms Massey Licata:

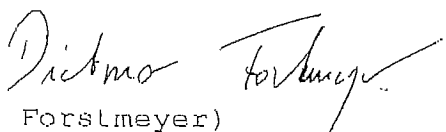
On February 12, 2007, Frommer Lawrence & Haug LLP transferred the above file to your firm. Tomorrow, February 21, 2007, is the deadline date for filing the response to missing requirements. Enclosed please find the following documents

- declaration
- assignment

signed by three inventors. The fourth inventor, Mr. Thomas Rillmann, refuses to sign said documents. Further, said declaration cites the Frommer et al. address as address for correspondence. Please advise whether this will be acceptable to the USPTO or let us have your suggestions how to handle the situation via return facsimile.

Thank you very much for your assistance.

Very truly yours,

  
(Dr. Forstmeier)

Encls.  
a/m

Dipl. Ing. Dr. Peter Lieck  
Dipl. Chem. Dr. Hans D. Boeters  
Dipl. Ing. Dr. Bert Bauer (+2003)  
Dipl. Ing. Dr. Gertmar Forstmeier  
Dipl. Chem. Dr. Dietmar G. Forstmeier  
Dipl. Ing. Roland Veith

Thomas Er. Wieser Rillmann  
TECHNOL/WW

Dr. Forstmeier  
Dr. Forstmeier  
Dr. Forstmeier  
Dr. Forstmeier  
Dr. Forstmeier

*Licata & Tyrrell P.C.*

*Patent Attorneys*

*Translating Science into Invention®*

*66 E. Main Street*

*Marlton, New Jersey 08053*

Telephone: (856) 810-1515

Facsimile: (856) 810-1454

Web Site: [licataandtyrrell.com](http://licataandtyrrell.com)

Direct E-mail: [jmlicata@licataandtyrrell.com](mailto:jmlicata@licataandtyrrell.com)

February 23, 2007

Via Federal Express

Dr. Thomas Rillmann  
Gustav-Ulrich-Str. 46  
D-76753 Bellheim, Germany

RE: U.S. National Stage Patent Application entitled  
"Pharmaceutical Active-Ingredient-Containing Formulation  
with Coating"  
Serial No: 10/577,569      Filing Date:  
Your Ref: 16508  
Our Ref: BOE0004US.NP

Dear Dr. Rillmann:

Enclosed is connection with the above-referenced application  
are the following documents for signature:

- \* Declaration and Power of Attorney form to be signed and  
dated by you; and
- \* Assignment to be signed and dated by you.

Please note that if a change is made to any of the  
information contained in the above-referenced documents, each  
change must be initialed and dated. Please return these  
documents to our office at your earliest convenience, on or by  
**March 22, 2007.**

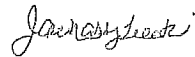
You can return the executed documents via e-mail, facsimile,  
regular U.S. mail or in the return Federal Express envelope  
provided. If a change is made to any of the information  
contained in the documents, each change must be initialed and  
dated.

February 23, 2007

Page 2

If you have any questions, please contact me.

Best regards,



Jane Massey Licata

JML:deb  
Enclosure

cc: Dr. Dietmar Forstmeyer  
Boeters & Lieck

From: Origin ID: WWDA (856) 810-1515  
Deborah Ehret  
Licata & Tyrell P.C.  
66 East Main Street



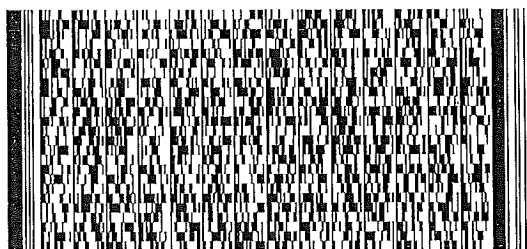
CL5012107/21/23

Marlton, NJ 08053  
UNITED STATES

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**Dr. Thomas Rillman**  
  
**Gustav-Ulrich-Str. 46**

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REF: BOE0004US.NP  
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DESC-2:  
DESC-3:  
DESC-4:  
EEI: NO EEI 30.37(a)  
COUNTRY MFG: US  
CARRIAGE VALUE: 0.00 USD  
CUSTOMS VALUE: USD  
T/C: S 165654455 D/T: S 165654455  
SIGN: Deborah Ehret  
EIN/VAT:

## IP ENVELOPE

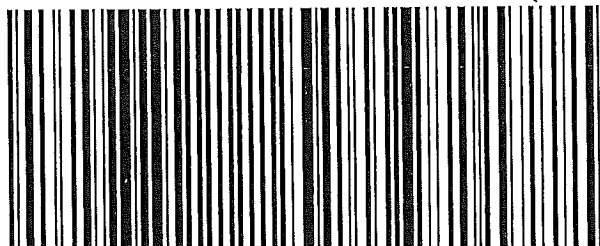
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FORM  
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76753 --DE

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The Warsaw Convention, as amended, will then govern and in most cases limit FedEx's liability for loss, delay of, or damage to your shipment. The Warsaw Convention, as amended, limits FedEx's liability. For example in the U.S. liability is limited to \$9.07 per pound (205 per kilogram), unless a higher value for carriage is declared as described below and you pay any applicable supplementary charges. The interpretation and operation of the Warsaw Convention's liability limits may vary in each country. There are no specific stopping places which are agreed to and FedEx reserves the right to route the shipment in any way FedEx deems appropriate. ROAD TRANSPORT NOTICE. Shipments transported solely by road to or from a country which is a party to the Warsaw Convention or the Contract for the International Carriage of Goods by Road (the "CMR") are subject to the terms and conditions of the CMR, notwithstanding any other provision of this Air Waybill to the contrary. For those shipments transported solely by road, if a conflict arises between the provisions of the CMR and this Air Waybill, the terms of the CMR shall prevail. LIMITATION OF LIABILITY. If not governed by the Warsaw Convention, the CMR, or other international treaties, laws, other government regulations, orders, or requirements, FedEx's maximum liability for damage, loss, delay, shortage, misdelivery, nondelivery, misinformation or failure to provide information in connection with your shipment is limited by this Agreement and as set out in the terms and conditions of the contract of carriage. Please refer to the contract of carriage set forth in the applicable FedEx Service Guide or its equivalent to determine the contractual limitation. FedEx does not provide cargo liability or all-risk insurance, but you may, at an additional charge for each additional U.S. \$100 (or equivalent local currency for the country of origin) of declared value for carriage. 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**Tracking number** 792937890918  
**Signed for by** ..F RILLMANN  
**Ship date** Feb 23, 2007  
**Delivery date** Feb 26, 2007 11:00 AM

**Reference** BOE0004US.NP  
**Destination** BELLHEIM DE  
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**Weight** 1.0 lbs.

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Feb 24, 2007	6:58 AM At local FedEx facility	BRUCHSAL DE	
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Feb 23, 2007	5:35 AM Departed FedEx location	MEMPHIS, TN	
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	11:37 PM Arrived at FedEx location	MEMPHIS, TN	
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**BOETERS & LIECK**

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TRADEMARK ATTORNEYS

FACSIMILE: 001-856-810-1454  
Licata & Tyrrell P.C.  
Attn.: Ms Jane Massey Licata  
66 E. Main Street  
Marlton, New Jersey 08053  
USA

April 19, 2007/St  
via facsimile

Your ref.: BOE004US.NP  
Our ref.: 16508  
US Patent Application No. 10/577 569  
Hexal AG

Dipl. Ing. H. Peter Lieck  
Dipl. Chem. Dr. Hans D. Boeters  
Dipl. Ing. Robert Bauer (2003)  
Dipl. Ing. Dr. Othmar Paustig  
Dipl. Chem. Dr. Dietmar G. Forstmeier  
Dipl. Ing. Roland Veith

Thomas Breitwieser Rechtsanwalt

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80331 München Germany  
Info@boeters-lieck.de  
Tel +49 (0) 89 23 23 659 0  
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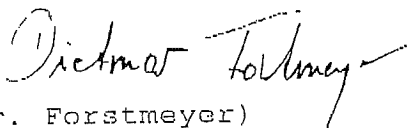
Dear Jane:

This is with reference to your letter of April 4, 2007.

We confirm that Dr. Rillmann's address is the latest known address and the correct one. Enclosed you will find a copy of a letter we sent him on March 12, 2007 whereupon he contacted Hexal AG and refused further cooperation.

We will try to let you have further information and evidence shortly.

Very truly yours,

  
(Dr. Forstmeier)

Encls.  
a/m



**Response To Notice To File Missing Parts Of Application  
Filing Date Granted (PTO-1533)(Large Entity)**

Docket No.  
**930008-2208 (BOE0004US.NP)**

In Re Application Of: **Klokkers et al.**

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
<b>10/577,569</b>	<b>Not Assigned</b>	<b>Not Assigned</b>	<b>26259</b>	<b>Not Assigned</b>	<b>6210</b>

Invention: **Pharmaceutical Active-Ingredient-Containing Formulation with Coating**

Mail Stop Missing Parts

COMMISSIONER FOR PATENTS:

This is a response to the Notice to File Missing Parts of Application - Filing Date Granted (PTO-1533) mailed on  
December 21, 2006  
*Date*

Enclosed herewith for filing are the following:

- ☒ A copy of the Notice to File Missing Parts of Application - Filing Date Granted (PTO-1533). **(REQUIRED)**
- ☐ An oath or declaration in compliance with 37 CFR 1.63, including residence information and identifying the application by the above Application Number and Filing Date.
- ☒ A properly signed oath or declaration in compliance with 37 CFR 1.63.
- ☐ An oath or declaration in compliance with 37 CFR 1.63 listing the names of all inventors and signed by the omitted inventor(s), identifying this application by the above Application Number and Filing Date.
- ☐ A verified English translation of the non-English language application papers as originally filed. It is requested that this translation be used as the copy for examination purposes in the United States Patent and Trademark Office.
- ☐ Other (list):

**Response To Notice To File Missing Parts Of Application  
Filing Date Granted (PTO-1533)(Large Entity)**

Docket No.  
**930008-2208 (BOE0004US.NP)**

In Re Application Of: **Klokkers et al.**

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
<b>10/577,569</b>	<b>Not Assigned</b>	<b>Not Assigned</b>	<b>26259</b>	<b>Not Assigned</b>	<b>6210</b>

Invention: **Pharmaceutical Active-Ingredient-Containing Formulation with Coating**

TO THE COMMISSIONER FOR PATENTS:

Mail Stop Missing Parts

☐ Completion of application fees as calculated below:

☐ Utility application basic fee \_\_\_\_\_

☐ Design application basic fee \_\_\_\_\_

☐ Search Fee \_\_\_\_\_

☐ Examination Fee \_\_\_\_\_

☐ Total number of independent claims = \_\_\_\_\_

☐ Total number of claims = \_\_\_\_\_

☐ Multiple dependent claims \_\_\_\_\_

☒ Surcharge for late payment of filing fee and/or late filing of original declaration or oath **\$130.00**

☐ Petition and fee for filing by other than all the inventors or a person not the inventor \_\_\_\_\_

☐ Fee for processing an application filed with a non-English language specification \_\_\_\_\_

☐ Fee for processing and retention of application \_\_\_\_\_

Total completion of application fees \_\_\_\_\_

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a response to the above-identified Notice to File Missing Parts of Application. The requested extension is as follows (check time period desired). If an additional time extension is required, please consider this a petition therefor.

☐ One month    ☐ Two months    ☐ Three months    ☐ Four months    ☒ Five months

from: February 22, 2007  
Date

until: July 21, 2007  
Date

Total time extension fees **\$2,160.00**

Total fees due **\$2,290.00**

**Response To Notice To File Missing Parts Of Application  
Filing Date Granted (PTO-1533) (Large Entity)**

Docket No.  
**930008-2208 (BOE0004US.NP)**

In Re Application Of: **Klokkers et al.**

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
<b>10/577,569</b>	<b>Not Assigned</b>	<b>Not Assigned</b>	<b>26259</b>	<b>Not Assigned</b>	<b>6210</b>

Invention: **Pharmaceutical Active-Ingredient-Containing Formulation with Coating**

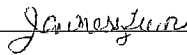
TO THE COMMISSIONER FOR PATENTS:

Mail Stop Missing Parts

The fee of **\$2,290.00** is to be paid as follows:

- ☐ A check in the amount of the fee is enclosed.
- ☐ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account No.
- ☒ If an additional extension of time is required, please consider this a petition therefor and charge any additional fees which may be required to Deposit Account No. **50-1619**
- ☒ Payment by credit card. Form PTO-2038 is attached.

**WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**

  
Signature

Dated: **July 17, 2007**

**Jane Massey Licata, Reg. No. 32,257  
Kathleen A. Tyrrell, Reg. No. 38,350  
Licata & Tyrrell P.C.  
66 E. Main Street  
Marlton, New Jersey 08053  
Telephone: (856) 810-1515  
Facsimile: (856) 810-1454**

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on

\_\_\_\_\_  
(Date)

\_\_\_\_\_  
Signature of Person Mailing Correspondence

\_\_\_\_\_  
Typed or Printed Name of Person Mailing Correspondence

CC:



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
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U.S. APPLICATION NUMBER NO. 10/577,569	FIRST NAMED APPLICANT Karin Klokke FROMMER, LAWRENCE & HAUG, LLP	ATTY. DOCKET NO. 930008-2208
---	---	---------------------------------

INTERNATIONAL APPLICATION NO.

PCT/EP04/12230

I.A. FILING DATE

10/28/2004

PRIORITY DATE

10/31/2003

Ronald R. Santucci  
 Frommer Lawrence & Haug  
 745 Fifth Avenue  
 New York, NY 10151

Docket System  
 Status Report  
 Docket Book

CONFIRMATION NO. 6210

371 FORMALITIES LETTER



\*OC000000021674468\*

DOCKETED

Date Mailed: 12/21/2006

2-21-07  
 7-21-07

### NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 04/27/2006
- English Translation of the IA filed on 04/27/2006
- Copy of the International Search Report filed on 04/27/2006
- Copy of IPE Report filed on 04/27/2006
- Preliminary Amendments filed on 04/27/2006
- Information Disclosure Statements filed on 04/27/2006
- Oath or Declaration filed on 04/27/2006
- U.S. Basic National Fees filed on 04/27/2006
- Priority Documents filed on 04/27/2006

The applicant needs to satisfy supplemental fees problems indicated below.

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date. The current oath or declaration does not comply with 37 CFR 1.497(a) and (b) in that it:
  - is not executed in accordance with either 37 CFR 1.66 or 37 CFR 1.68.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.492(h) of \$130 for a non-small entity, must be submitted with the missing items identified in this letter.

SUMMARY OF FEES DUE:

Total additional fees required for this application is **\$130** for a Large Entity:

- **\$130** Surcharge.

**ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.**

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web.

<https://portal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html>

For more information about EFS-Web please call the USPTO Electronic Business Center at **1-866-217-9197** or visit our website at <http://www.uspto.gov/ebc>.

**If you are not using EFS-Web to submit your reply, you must include a copy of this notice.**

CHARITTA A BURT

Telephone: (703) 308-9140 EXT 207

PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/577,569	PCT/EP04/12230	930008-2208

20. FEB. 2007 12:19

8024 908 2198

NR. 8530 S. 2/5

FLH Docket No. 930008-2208

# DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY

(Under 37 CFR § 1.63; includes reference to PCT International Applications)

As a below named inventor, I hereby declare that:

My residence, resident, mailing address and citizenship are as stated below next to my name.

I believe I am an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention ENTITLED:

PHARMACEUTICAL ACTIVE-INGREDIENT-CONTAINING FORMULATION WITH COATING

the specification of which:

- ☐ is attached hereto  
☒ was filed on \_\_\_\_\_ as:  
☒ United States Application Serial No. \_\_\_\_\_  
☒ as a National Phase or Continuation or Continuation-in-Part or Divisional of  
PCT Application No. PCT/EP2004/012230, filed October 28, 2004  
and designating the U.S., and published as WO 2005/041934 A on May 12, 2005  
☐ with amendments through \_\_\_\_\_ (if applicable, give details).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56.

Thereby claim foreign priority benefits under Title 35, United States Code § 119 of any foreign application(s) for patent or inventor's certificate or of any PCT International application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application for patent or inventor's certificate or any PCT International applications designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) on which priority is claimed:

Prior Foreign/PCT Application(s) [list additional applications on separate page]:

Country (or PCT)	Application Number:	Filed (Day/Month/Year)	Priority Claimed:	
			Yes	No
DE (Germany)	103 51 301.9	31/10/2003	<input checked="" type="checkbox"/>	<input type="checkbox"/>
DE (Germany)	10 2004 014 828.7	24/03/2004	<input checked="" type="checkbox"/>	<input type="checkbox"/>

I hereby claim the benefit under 35 U.S.C. § 119(e) of any United States application listed below:

(Application Number) (Filing Date)

I hereby claim the benefit under Title 35, United States Code § 120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code § 112, I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

20. FEB. 2007 12:20

8024 908 2198

NR. 853 S. 3/5

FLH Docket No. 930008-2208

Prior U.S. (or U.S.-designating PCT) Application(s) [list additional applications on separate page]:

U.S. Serial No.: Filed (Day/Month/Year) PCT Application No. Status (patented, pending, abandoned)

I hereby appoint Ronald R. Santucci, Registration No. 28,988, and Frommer Lawrence & Haug LLP, or their duly appointed associate, my attorneys, with full power of substitution and revocation, to prosecute this application, to make alterations and amendments therein, to file continuation and divisional applications thereof, to receive the Patent, and to transact all business in the Patent and Trademark Office and in the Courts in connection therewith, and to insert the Serial Number of the application in the space provided above, and specify that all communications about the application are to be directed to the following correspondence address:

Ronald R. Santucci, Esq.  
c/o FROMMER LAWRENCE & HAUG LLP  
745 Fifth Avenue  
New York, NY 10151

Direct all telephone calls to: (212) 588-0800  
to the attention of: Ronald R. Santucci

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

INVENTOR(S):

X Signature: Karin Klockers

Date: Aug 28, 2006

Full name of sole or first inventor:

Karin KLOCKERS

Residence:

Feldkirchen-Westerham, Germany

Mailing Address:

Eichenstr. 2a, D-83620, Feldkirchen-Westerham, Germany

Citizenship:

German

X Signature: Marion Zellner

Date: 20.08.2006

Full name of 2nd joint inventor (if any): Marion ZELLNER

Residence:

Egmating, Germany

Mailing Address:

Binsberg 15, D-85658, Egmating, Germany

Citizenship:

German

X Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Full name of 3rd joint inventor (if any): Thomas RILLMAN

Residence:

Bellheim, Germany

Mailing Address:

Gustav-Ullrich-Str. 46, D-76753, Bellheim, Germany

Citizenship:

German

20. FEB: 2007 12:20

8024 908 2198

NR. 853

S. 4/5

FLH Docket No. 930008-2208

X Signature:

Andreas Dauer

Date:

04/03/06

Full name of 4th joint inventor (if any): Andreas DAUER

Mailing Address:

Julius-von-Niethammer-Str. 16, D-83052 Heufeld, Germany

Residence:

Heufeld, Germany

Citizenship:

German



**COMBINED DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY**  
(Includes Reference to PCT International Applications)

ATTORNEY DOCKET NUMBER  
930008-2208

As a below named inventor, I hereby declare that:  
My residence, post office address and citizenship are as stated below next to my name.  
I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

**PHARMACEUTICAL ACTIVE-INGREDIENT-CONTAINING FORMULATION WITH COATING**

The specification of which (check only one item below):

( ) is attached hereto.

(X ) was filed as United States application

Serial No. \_\_\_\_\_

on \_\_\_\_\_

and was amended

on \_\_\_\_\_

(if applicable)

(X ) was filed as PCT international application

Number PCT/EP2004/012230

on Oct. 28; 2004

and was amended under PCT Article 19

on \_\_\_\_\_

(if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is known to me or other person(s) involved in the preparation or prosecution of this application to be material to the examination of this application and to patentability as defined in Title 37, Code of Federal Regulations, §1.56.

I hereby authorize the U.S. attorney or agent named herein to accept and follow instructions from \_\_\_\_\_

as to any action taken in the Patent and Trademark Office regarding this application without direct communication between the U.S. attorney or agent and the undersigned. In the event of a change in the persons from whom instructions may be taken, the U.S. attorney or agent named herein will be so notified by the undersigned.

I hereby claim benefits under Title 35, United States Code, §119 of any application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor(s) certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:

**PRIOR FOREIGN/PCT APPLICATION(S) AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. 119**

COUNTRY (if PCT, indicate "PCT")	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 35 USC 119
Germany	103 51 301.9	31. October 2003	x YES NO
Germany	102004014828.7	24. March 2004	x YES NO

**Combined Declaration For Patent Application and Power of Attorney (Continued)**  
(Includes Reference to PCT International Applications)

ATTORNEY DOCKET NUMBER

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application:

**PRIOR U.S. APPLICATIONS OR PCT INTERNATIONAL APPLICATIONS DESIGNATING THE U.S. BENEFIT UNDER 35 U.S.C. 120**

U.S. APPLICATIONS		STATUS (Check one)		
U.S. APPLICATION NUMBER	U.S. FILING DATE	PATENTED	PENDING	ABANDONED

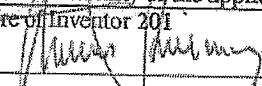
PCT APPLICATIONS DESIGNATING THE U.S.			
PCT APPLICATION NUMBER	PCT FILING DATE	U.S. SERIAL NUMBER ASSIGNED (if any)	

**POWER OF ATTORNEY:** As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. (Name and registration number)  
Ronald R. Santucci, Reg.No. 28,988

Send Correspondence to: Ronad R. Santucci, Esq. Te.: 212 588-0800  
c/o FROMMER LAWRENCE & HAUGH LLP  
745 Fifth Avenue, New York NY 10151

2 0 1	FULL NAME OF INVENTOR	FAMILY NAME RILLMANN	GIVEN NAME Thomas	SECOND GIVEN NAME
	RESIDENCE & CITIZENSHIP	CITY D-76753 Bellheim	STATE OR FOREIGN COUNTRY Germany	COUNTRY OF CITIZENSHIP Germany
	POST OFFICE ADDRESS	POST OFFICE ADDRESS Gustav-Ullrich-Str.46	CITY D-76753 Bellheim	STATE & ZIP CODE/COUNTRY
2 0 2	FULL NAME OF INVENTOR	FAMILY NAME	GIVEN NAME	SECOND GIVEN NAME
	RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE & ZIP CODE/COUNTRY
2 0 3	FULL NAME OF INVENTOR	FAMILY NAME	GIVEN NAME	SECOND GIVEN NAME
	RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE & ZIP CODE/COUNTRY

I hereby declare under penalty of perjury under the laws of the United States of America that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine and imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Signature of Inventor 201 X 	Signature of Inventor 202	Signature of Inventor 203
Date X 09.07.2007	Date	Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: BOE0004US.NP  
Inventors: Klokke et al.  
Serial No.: 10/577,569  
Filing Date: Not Assigned  
Examiner: Not Assigned  
Customer No: 26259  
Group Art Unit: Not Assigned  
Confirmation No: 6210  
Title: Pharmaceutical Active-Ingredient-  
Containing Formulation with Coating

Electronically Submitted via EFS-Web

Date: October 4, 2007

I hereby certify that this paper is being electronically  
submitted on the date indicated above to the  
Commissioner for Patents, U.S. Patent &  
Trademark Office

By Jane Massey Licata  
Typed Name: Jane Massey Licata, Reg. No. 32,257

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Declaration of Hubert Leger

I, Hubert Leger, of Hexal AG, Industriestrasse 25, 83607  
Holzkirchen, Germany state the following:

1. I am the Head of Patents Sandoz Development Center at  
the Holzkirchen site of Hexal AG ("the Employer"). I  
have held this position since 1 January 2006. I am  
duly authorised to make this Statement on behalf of the  
Employer who has also acquired rights in US Patent

Attorney Docket No: BOE0004US.NP  
Inventors: Klokke et al.  
Serial No.: 10/577,569  
Filing Date: Not Assigned  
Page 2

Application No. 01/577,569 (the "Application") by virtue of assignment. The information in this Affidavit is taken from the Employer's records, to which I have full access, and from my own personal knowledge.

2. This Affidavit is made in support of a Petition Under 37 CFR §1.47(a), to accept the Application without the signature of one of the co-inventors - Dr. Thomas Rillmann.
3. On 23 February 2007 a Federal Express package was sent to Dr. Rillmann at his last known address of: Gustav-Ullrich-Str. 46, 76753 Bellheim, Germany, enclosing, for signature, a copy of the Declaration for Patent Application, a Power of Attorney and an Assignment form. Receipt of this package was confirmed by the Receptionist/Front Desk on 26 February 2007 and this confirmation was returned to the US attorneys Licata & Tyrrell P.C. who are handling the prosecution of the Application, on our behalf, in the United States. Attached are copies of the letter, Federal Express label and confirmation of delivery.
4. Dr. Rillmann did not return any of these documents and in the absence of a response from him, I contacted him in early 2007 to suggest that we have a meeting to resolve the outstanding issues regarding the Application.
5. Dr. Rillmann agreed to attend a meeting at Hexal AG in Holzkirchen which took place on Friday 9<sup>th</sup> March 2007. The meeting was attended by myself, Dr. Rillmann, Dr.

Attorney Docket No: BOE0004US.NP  
Inventors: Klokke et al.  
Serial No.: 10/577,569  
Filing Date: Not Assigned  
Page 3

Zeh-Herwerth and Dr. Karin Klokke, one of the other inventors named on the Application

6. During the meeting Dr. Rillman indicated that he was unwilling to sign documents in relation to the Application.
7. On 25 April 2007 I received a letter from a firm of German Patent Attorneys acting for Dr. Rillman. In the letter, Dr. Rillman's attorneys indicated that Dr. Rillman would not sign the Declaration in its present form because of an on going issue regarding inventorship.
8. On 23 May 2007, at my direction, my colleague, Robin Ellis, sent a letter to Dr. Rillmann's attorneys, enclosing the Declaration and requesting that it be forwarded to their client (see Attached).
9. On 20 June 2007, at my direction, our assistant Frau Andrea Hundsdoerfer spoke with Dr. Rillmann's patent attorney, Herr Dr. Steffen Lenz, who confirmed that the letter of 23 May 2007 had been forwarded to, and received by, Dr. Rillmann. Herr Dr. Lenz also informed Frau Hundsdoerfer that we should expect to receive an executed Declaration by the end of the week commencing 25 June 2007.
10. At my instruction, a further reminder letter was sent by facsimile and email to Herr Dr. Lenz on 5 July 2007 but as of 11 July 2007, the Declaration had still not been received.

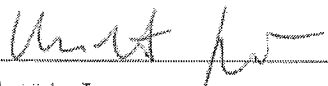
Attorney Docket No: BOE0004US.NP  
Inventors: Klokke et al.  
Serial No.: 10/577,569  
Filing Date: Not Assigned  
Page 4

11. On 13 July 2007, I received an executed, amended, version of the Declaration from Herr Dr. Lenz which my colleague, Robin Ellis, forwarded to our US attorneys for filing at the USPTO. Before executing the Declaration, Dr. Rillmann removed the names of the other three inventors.
12. On July 17, 2007, a response to Missing Parts was filed with two Declarations: one signed by the other co-inventors and one prepared and signed by Dr. Rillmann.
13. On 5 September 2007, a decision was issued by the USPTO stating that the Declaration prepared and signed by Dr. Rillmann was "not in compliance with 37 CFR 1.497(a)-(b) since it does not identify all of the inventors". A deadline of 1 month from the mailing date of this decision was set to remedy this deficiency but due to the notice being sent to the incorrect US attorney, I only became aware of this decision on 1 October 2007.
14. On 2 October 2007, my colleague, Robin Ellis, sent a facsimile to Dr. Rillmann's attorney, informing him of the problem with the Declaration executed by Dr. Rillmann, and requesting that Dr. Rillmann return an executed version of the original Declaration before 4 October 2007.
15. As of 4 October 2007, the executed Declaration had not been received from either Dr. Rillmann or his attorney.

Attorney Docket No.: BOE0004US.NP  
Inventors: Klokke et al.  
Serial No.: 10/577,569  
Filing Date: Not Assigned  
Page 5

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,

  
Hubert Leger

Date: October 4, 2007

LICATA & TYRRELL P.C.  
66 E. Main Street  
Marlton, NJ 08053

(856) 810-1515

BOETERS &amp; LIECK

- PATENTANWÄLTE  
- EUROPEAN PATENT ATTORNEYS  
- TRADEMARK ATTORNEYS

Herrn

Dr. Thomas Rillmann

Gustav-Ullrich-Str. 46

76753 Bellheim

12. März 2007/St

Dipl.-Ing. H. Peter Lieck  
Dipl. Chem. Dr. Hans G. Rillmann  
Dipl.-Ing. Robert Rillmann  
Dipl.-Ing. Dr. Olaf Rillmann  
Dipl. Chem. Dr. Dietrich Rillmann  
Dipl. Ing. Rillmann

Thomas Rillmann

RECHNUNG

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Unser Zeichen: 16503

Kanadische Patentanmeldung Nr. 2 543 689

auf Basis von DE 103 51 301.9, DE 10 2004 014 828.7

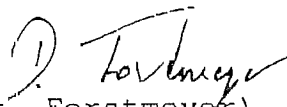
und PCT/EP 2004/012230

Klokkers et al.; Pharmaceutical active-ingredient-containing  
formulation with coating

Sehr geehrter Herr Dr. Rillmann!

In obengenannter Patentanmeldung läuft am 26. April 2007 die Frist zur Einreichung des Assignments beim Kanadischen Patentamt ab. Bitte lassen Sie uns wissen, ob Sie in obengenannter Patentanmeldung sowie in den parallelen Akten der Patentfamilie gewillt sind, die nötigen Unterschriften zu leisten. Bitte beachten Sie, daß die Anmeldungen ohne Ihre Unterschrift möglicherweise als zurückgenommen gelten und eventuell Schadenersatzforderungen auf Sie zukommen könnten.

Mit freundlichen Grüßen

  
(Dr. Forstmeyer)  
Patentanwalt



FAX HEADER. +49 8024 908 2190

ABGEGABET/ABGESTREICHERT : 20. NOV. 2007 16:39

DAT.	MODUS	OPTION
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ASSOCIATES

[illegible]

25  
 26  
 27  
 28  
 29

598 SPEICHER SENDEN

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OK

6/8

FBIHQ  
FBI - NEW YORK  
FBI - BOSTON  
FBI - PHOENIX  
FBI - SAN FRANCISCO  
FBI - SEATTLE  
FBI - TAMPA  
FBI - WASHINGTON FIELD  
FBI - WASHINGTON METRO  
FBI - WASHINGTON STATE  
FBI - YAKIMA

1-23 RISE 171  
 1-43 SINE FAX-VKREINDUNG



# HEXAL AG

**Vorab per Telefax: 07 21 / 9 43 28 40**

LIGHT

Patentariväite

z. Hd. Herrn Dipl.-Ing. Lenz

Postfach 41 07 60

D-76207 Karlsruhe

Ansprechpartner: Robin Ellis  
Tel: +49 (0) 80 24 / 9 08 - 21 98  
Fax: +49 (0) 80 24 / 9 08 - 21 98  
e-mail: robin.ellis@quandoz.com

Holzkirchen, 20 November 2007

Your Ref: A3001.4 Lz/vt

Hexal Ref: 50786-US-PCT

US patent application no. 10/577 569

based on PCT/EP 2004/012230

**"Pharmaceutical active-ingredient containing formulation with coating"**

Dear Mr Lenz,

I write further to my letter of 2 October 2007 (attached), in which I informed you of the deficiencies reported by the USPTO in relation to the amended Declaration and Power of Attorney, executed by your client, Dr. Thomas Rillmann.

We have, fortunately, been set an extended deadline of **7 January 2007** to file and executed version of the original Declaration, in which all four inventors are named, to ensure that US patent application no. 10/577 569 is not deemed abandoned.

If your client is not willing to sign this Declaration, please let us know well in advance of the 7 January 2007 deadline so we can communicate this information to the US attorneys handling this case.

Please communicate to your client that failure to file this Declaration is likely to result in the application being deemed abandoned. Please send confirmation of receipt of this letter.

Yours sincerely,

HEXAL AG

Robin Ellis  
Patent Attorney

SENDERBERICHT ( 13. DEZ. 2007 14:59 )

FAX HEADER: +49 8024 908 2198

GESENDET/ABGESPEICHERT : 13. DEZ. 2007 14:58

DAT.	MODUS	OPTION	ADRESSE	ERGEBN.	SEITE
082	SPEICHER SENDEL		007219432040	OK	1/1

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G=4} KEITH F&S-VFKK 1630165



# HEXAL AG

Vorab per Telefax: 07 21 / 9 43 28 40

LICHTI  
 Patentanwälte  
 z. Hd. Herrn Dipl.-Ing. Lenz  
 Postfach 41 07 60  
 D-76207 Karlsruhe

REMINDER

**Ansprechpartner: Robin Ellis**  
Tel: +49 (0) 80 24 79 08 – 21 98  
Fax: +49 (0) 80 24 79 08 – 21 98  
e-mail: [robin.ellis@beandoz.com](mailto:robin.ellis@beandoz.com)

Holzkirchen, 20 November 2007

Your Ref: A3001.4 Lz/vt  
Hexal Ref: 50786-US-PCT  
US patent application no. 10/577 569  
based on PCT/EP 2004/012230  
"Pharmaceutical active-ingredient containing formulation with coating"

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Yours sincerely,

HEXAL AG

Robin Ellis  
Patent Attorney

X X X SENDERBERICHT ( 4. JAN. 2008 9:35 ) 35 20 35

FAX HEADERS: 140 0024 S02 2100

GESCHIEDT. ABGESCHLOSSEN : 4. JAN. 2008 9:35

DAI, MOONS

**ORIGIN**

## DISCUSSION

## RESULTS

<sup>a</sup> Data of  
<sup>b</sup> Brown  
<sup>c</sup> C...  
<sup>d</sup> C...  
<sup>e</sup> C...  
<sup>f</sup> C...

733 SPEICHER ZENDEN

007219432040

OK

[illegible]

E-23 RESILIZ  
 E-42 BELINE EASY-TO-RE-NEURS



# HEXALAG

**Vorab per Telefax: 07 21 / 9 43 28 40**

# LIGHT

Patentanwälte

z. Hd. Herrn Dipl.-Ing. Lenz

Postfach 41 07 60

D-76207 Karlsruhe

**REMINDER**

**Ansprechpartner: Robin Ellis**  
Tel: +49 (0) 80 24 / 9 08 – 21 96  
Fax: +49 (0) 80 24 / 9 08 – 21 98  
e-mail: [robin.ellis@sandoz.com](mailto:robin.ellis@sandoz.com)

Holzkirchen, ~~20 November 2007~~  
4 January 2008

Your Ref: A3001.4 Lz/vt  
Hexal Ref: 50786-US-PCT  
US patent application no. 10/577 569  
based on PCT/EP 2004/012230  
"Pharmaceutical active-ingredient containing formulation with coating"

Dear Mr Lenz,

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We have, fortunately, been set an extended deadline of **7 January 2007** to file and executed version of the original Declaration, in which all four inventors are named, to ensure that US patent application no. 10/577 569 is not deemed abandoned.

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Please communicate to your client that failure to file this Declaration is likely to result in the application being deemed abandoned. Please send confirmation of receipt of this letter.

Yours sincerely,

HEXAL AG

Robin Ellis  
Patent Attorney

FAX HEADER: +49 8024 908 2198

GESENDET/ABGESPEICHERT : 23. MAI. 2007 12:50

DAT. MODUS	OPTION	ADRESSE	ERGEBN.	SEITE
069	SPEICHER SENDE	007219432840	OK	4/4

FUNKFACH:  
 1-1) ÜBERTRAGUNGSEHRER  
 1-3) KEINE ANTWORT

1-2) BENUTZT  
 1-4) KEINE FAX-VERBINDUNG

# HEXAL AG



HEXAL AG - Postfach 1263 - 83602 Holzkirchen

**Vorab per Telefax: 07 21 / 9 43 28 40**

LICHT

Patentanwälte

z. Hd. Herrn Dipl.-Ing. Lenz

Postfach 41 07 60

D-76207 Karlsruhe

Ansprechpartner: Andrea Hundsdoerfer  
 Tel: +49 (0) 80 24 / 9 08 - 15 03  
 Fax: +49 (0) 80 24 / 9 08 - 21 98  
 e-mail: andrea.hundsdoerfer@sandoz.com

Holzkirchen, 23. Mai 2007

Ihr Zeichen: A3001.4 Lz/vt

PCT/EP 2004/012230

„Pharmaceutical active-ingridient containing formulation with coating“

hier: Arbeitnehmererfinder Dr. Thomas Rillmann

Sehr geehrter Herr Dipl.-Ing. Steffen Lenz,

Wir beziehen uns auf Ihre Schreiben in o. g. Angelegenheit und nehmen zur Kenntnis, daß Sie Herrn Dr. Thomas Rillmann in dieser Angelegenheit vertreten.

In der Anlage erhalten Sie eine „Declaration for Patent application and Power of Attorney“ bezüglich der US-Anmeldung Nr. 10/577 569. Eine Kopie dieser Declaration wurde bereits per Federal Express am 23.02.2007 an Herrn Rillmann gesandt.

Bitte bestätigen Sie uns, daß Sie die „Declaration for Patent application and Power of Attorney“ erhalten und an Herrn Rillmann zur Unterschrift weitergeleitet haben.

Wir bitten um Rücksendung der von Herrn Rillmann unterzeichneten „Declaration“ an uns so bald wie möglich.

Mit freundlichen Grüßen

HEXAL AG

*Robin Ellis*

Robin Ellis  
 Patente SDC Holzkirchen

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Sitz:  
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 Registergericht: München  
 HRB 110375  
 Ust-Id Nr DE 31179111

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: BOE0004US.NP  
Inventors: Klokke et al.  
Serial No.: 10/577,569  
Filing Date: Not Assigned  
Examiner: Not Assigned  
Customer No: 26259  
Group Art Unit: Not Assigned  
Confirmation No: 6210  
Title: Pharmaceutical Active-Ingredient-  
Containing Formulation with Coating

Electronically Submitted via EFS-Web

Date: January 4, 2008

I hereby certify that this paper is being electronically  
submitted on the date indicated above to the  
Commissioner for Patents, U.S. Patent &  
Trademark Office

By Jane Massey Licata  
Typed Name: Jane Massey Licata, Reg. No. 32,257

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Declaration of Hubert Leger

I, Hubert Leger, of Hexal AG, Industriestrasse 25, 83607  
Holzkirchen, Germany state the following:

Attorney Docket No.: BOE0004US.NP  
Inventors: Klokke et al.  
Serial No.: 10/577,569  
Filing Date: Not Assigned  
Page 2

1. I am the Head of Patents Sandoz Development Center at the Holzkirchen site of Hexal AG ("the Employer"). I have held this position since 1 January 2006. I am duly authorised to make this Statement on behalf of the Employer who has also acquired rights in US Patent Application No. 01/577,569 (the "Application") by virtue of assignment. The information in this Affidavit is taken from the Employer's records, to which I have full access, and from my own personal knowledge.
2. This Affidavit is made in support of a Petition Under 37 CFR \$1.47(a), to accept the Application without the signature of one of the co-inventors - Dr. Thomas Rillmann.
3. On 23 February 2007 a Federal Express package was sent to Dr. Rillmann at his last known address of: Gustav-Ullrich-Str. 46, 76753 Bellheim, Germany, enclosing, for signature, a copy of the Declaration for Patent Application, a Power of Attorney and an Assignment form. Receipt of this package was confirmed by the Receptionist/Front Desk on 26 February 2007 and this confirmation was returned to the US attorneys Licata & Tyrrell P.C. who are handling the prosecution of the Application, on our behalf, in the United States. Attached are copies of the letter, Federal Express label and confirmation of delivery.
4. Dr. Rillmann did not return any of these documents and in the absence of a response from him, I contacted him in early

Attorney Docket No.: BOE0004US.NP  
Inventors: Klokke et al.  
Serial No.: 10/577,569  
Filing Date: Not Assigned  
Page 3

2007 to suggest that we have a meeting to resolve the outstanding issues regarding the Application.

5. Dr. Rillmann agreed to attend a meeting at Hexal AG in Holzkirchen which took place on Friday 9<sup>th</sup> March 2007. The meeting was attended by myself, Dr. Rillmann, Dr. Zeh-Herwerth and Dr. Karin Klokke, one of the other inventors named on the Application
6. During the meeting Dr. Rillman indicated that he was unwilling to sign documents in relation to the Application.
7. On 25 April 2007 I received a letter from a firm of German Patent Attorneys acting for Dr. Rillman. In the letter, Dr. Rillman's attorneys indicated that Dr. Rillman would not sign the Declaration in its present form because of an ongoing issue regarding inventorship.
8. On 23 May 2007, at my direction, my colleague, Robin Ellis, sent a letter to Dr. Rillmann's attorneys, enclosing the Declaration and requesting that it be forwarded to their client (see Attached).
9. On 20 June 2007, at my direction, our assistant Frau Andrea Hundsdorfer spoke with Dr. Rillmann's patent attorney, Herr Dr. Steffen Lenz, who confirmed that the letter of 23 May 2007 had been forwarded to, and received by, Dr. Rillmann. Herr Dr. Lenz also informed Frau Hundsdorfer that we should

Attorney Docket No.: BOE0004US.NP  
Inventors: Klokke et al.  
Serial No.: 10/577,569  
Filing Date: Not Assigned  
Page 4

expect to receive an executed Declaration by the end of the week commencing 25 June 2007.

10. At my instruction, a further reminder letter was sent by facsimile and email to Herr Dr. Lenz on 5 July 2007 but as of 11 July 2007, the Declaration had still not been received.
11. On 13 July 2007, I received an executed, amended, version of the Declaration from Herr Dr. Lenz which my colleague, Robin Ellis, forwarded to our US attorneys for filing at the USPTO. Before executing the Declaration, Dr. Rillmann removed the names of the other three inventors.
12. On July 17, 2007, a response to Missing Parts was filed with two Declarations: one signed by the other co-inventors and one prepared and signed by Dr. Rillmann.
13. On 5 September 2007, a decision was issued by the USPTO stating that the Declaration prepared and signed by Dr. Rillmann was "not in compliance with 37 CFR 1.497(a)-(b) since it does not identify all of the inventors". A deadline of 1 month from the mailing date of this decision was set to remedy this deficiency but due to the notice being sent to the incorrect US attorney, I only became aware of this decision on 1 October 2007.



Attorney Docket No.: BOE0004US.NP  
Inventors: Klokke et al.  
Serial No.: 10/577,569  
Filing Date: Not Assigned  
Page 5

14. On 2 October 2007, my colleague, Robin Ellis, sent a facsimile to Dr. Rillmann's attorney, informing him of the problem with the Declaration executed by Dr. Rillmann, and requesting that Dr. Rillmann return an executed version of the original Declaration before 4 October 2007.
15. Dr. Rillmann did not sign the Declaration by 4 October 2007 and has continued to refuse to sign to date.
16. On November 20 and December 13, 2007 and January 4, 2008, letters and reminders were sent to Dr. Rillmann's attorney requesting that Dr. Rillmann cooperate and execute the Declaration (see Attached). Neither Dr. Rillmann nor his attorney has responded to this request. Dr. Rillmann has failed to agree to sign the Declaration after repeated requests over the past year.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under

Attorney Docket No.: BOE0004US.NP  
Inventors: Klokke et al.  
Serial No.: 10/577,569  
Filing Date: Not Assigned  
Page 6

Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,

  
Hubert Leger

Date: January 04, 2008

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